UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

FEDERAL TRADE COMMISSION and

THE PEOPLE OF THE STATE OF NEW YORK, by LETITIA JAMES, Attorney General of the State of New York,

Plaintiffs,

v.

QUINCY BIOSCIENCE HOLDING COMPANY, INC., a corporation;

QUINCY BIOSCIENCE, LLC, a limited liability company;

PREVAGEN, INC., a corporation d/b/a/ SUGAR RIVER SUPPLEMENTS;

QUINCY BIOSCIENCE MANUFACTURING, LLC, a limited liability company; and

MARK UNDERWOOD, individually and as an officer of QUINCY BIOSCIENCE HOLDING COMPANY, INC., QUINCY BIOSCIENCE, LLC, and PREVAGEN, INC.,

Defendants.

Case No. 1:17-cv-00124-LLS

DEFENDANTS' STATEMENT OF MATERIAL FACTS
PURSUANT TO LOCAL CIVIL RULE 56.1

Pursuant to Federal Rule of Civil Procedure 56 and Local Civil Rule 56.1, Defendants Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC, Prevagen, Inc., Quincy Bioscience Manufacturing, LLC, and Mark Underwood ("Defendants") hereby submit the following statement of material facts as to which Defendants contend there is no genuine issue and that entitle Defendants to judgment as a matter of law.

THE COMPLAINT

1. On January 9, 2017, plaintiffs the FTC and NYAG (collectively, "Plaintiffs") filed the Complaint for Permanent Injunction and Other Equitable Relief ("Complaint" or "Compl."). (ECF No. 1.)

2. The Complaint challenges the following advertising statements concerning Prevagen: Prevagen improves memory; Prevagen improves memory within 90 days; Prevagen reduces memory problem associated with aging; Prevagen provides other cognitive benefits, including, but not limited to, healthy brain function, a sharper mind, and clearer thinking; and that Prevagen is "clinically shown" to have such effects (collectively, the "Challenged Claims"). (Compl. ¶¶ 36, 39, 42, 44.)

THE PARTIES

3. The Federal Trade Commission ("FTC") is an independent agency of the United States Government created by statute. (15 U.S.C. §§ 41-58; Compl. ¶ 6.)

4. The People of the State of New York, by Letitia James, Attorney General of the State of New York ("NYAG") bring this action under NY Exec. Law § 63 and NY GBL §§ 349 and 350. (Compl. ¶ 8.)

5. Quincy Bioscience Holding Company, Inc. is a Wisconsin corporation with principal place of business in Madison, Wisconsin. (Compl. ¶ 9.)

6. Quincy Bioscience Holding Company, Inc., wholly owns: Prevagen, Inc., which markets and sells Prevagen Products; Quincy Bioscience Manufacturing, LLC; and Quincy Bioscience, LLC. (ECF 213 ¶¶ 4, 12.)

7. Quincy Bioscience, LLC is a Wisconsin limited liability company with its principal place of business in Madison, Wisconsin. (Compl. ¶ 10.)

8. Quincy Bioscience Manufacturing, LLC is a Wisconsin limited liability company with its principal place of business in Madison, Wisconsin. (Compl. ¶ 12.)

9. Prevagen, Inc. is a Wisconsin corporation with its principal place of business in Madison, Wisconsin. (Compl. ¶ 11.)

10. Mark Underwood is the co-founder and President of Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC and Prevagen, Inc. (Compl. ¶ 13; Underwood Decl. ¶ 1.)

RELEVANT BACKGROUND CONCERNING PREVAGEN

11. Prevagen® is a dietary supplement. (Compl. ¶ 19; ECF 74 ¶ 19; Underwood Decl. ¶ 4; Olson Decl. ¶ 4 and Exs. A—F.)

12. Apoaequorin, one of the active ingredients in Prevagen, is a calcium-binding protein derived from aequorin, which was originally discovered in the aequorea victoria jellyfish. (Compl. ¶ 19; Underwood Decl. ¶ 5.)

13. The phrase "dietary supplement" has been on every single bottle of Prevagen that has been sold in the United States since its introduction to the market in 2007. (Olson Decl. ¶ 7 and Exs. A—F.)

14. Every package and label of Prevagen sold since 2007 contained the explicit statement that the product "is not intended to diagnose, treat, cure, or prevent any disease." (Compl. Exhibit A ¶ 27 at 10-11; Olson Decl. ¶ 7 and Exs. A—F; Graham Decl. Ex. E, Olson Tr. 172:4-13.)

15. In or around 2016, the Prevagen line of products were reformulated to include 50 micrograms of Vitamin D3. Prevagen Products that contain vitamin D3 contain 50 micrograms of vitamin D3 per capsule or chewable tablet, which is equivalent to 2000 IU of vitamin D. (Underwood Decl. ¶ 8; Graham Decl. Ex. GG, Defendants' Responses and Objections to

Plaintiffs' Second Set of Interrogatories dated June 8, 2020, at Response No. 8; Olson Decl. ¶ 10 and Exs. E.)

16. Prevagen's target market is, and always has been, healthy, older community dwelling adults who are cognitively normal or who have mild cognitive impairment due to the normal aging process. (Underwood Decl. ¶ 9 and Ex. Q at 2; Graham Decl. Ex. A, Lerner Indiv. Tr. 170:22—171:7; Graham Decl. Ex. B, Lerner 30(b)(6) Tr. 21:16-23, 22:4-11.)

MARKETING AND ADVERTISING OF PREVAGEN

17. Prevagen was first introduced for sale in the United States or around 2007. (Underwood Decl. ¶ 6.)

18. Between 2007 and the present, Prevagen has been sold in three different dosages (Regular Strength, Extra Strength, and Professional), two different formats (capsules and chewable tablets), two different sizes (30 and 60 count) and multiple different types of packages. (Underwood Decl. ¶ 7.)

19. Prevagen products do not have an expiration date. Prevagen is marketed and sold to consumers and non-consumers including, but not limited to, brick-and-mortar and online retailers, healthcare professionals, and pharmaceutical distributors. (Olson Decl. ¶¶ 9, 11.)

20. The labels for Prevagen products have changed numerous times since 2007. (Olson Decl. ¶ 12 and Exs. A—F.)

21. Beginning in or around 2007, the labels for Prevagen products contained the product descriptor "Jellyfish Fight Aging." Prevagen products with labels bearing the product descriptor "Jellyfish Fight Aging" were available for sale starting in September 2007. (Olson Decl. ¶¶ 13—15 and Ex. A.)

22. Beginning in or around 2008, the labels for Prevagen products contained the product descriptor: "Brain Cell Protection." Prevagen products with labels bearing the product descriptor "Brain Cell Protection" were available for sale starting in July 2008. (Olson Decl. ¶¶ 17—19 and Ex. B.)

23. Beginning in or around 2011, the labels for Prevagen Products contained the product descriptor "Clearer Thinking." Prevagen products with labels bearing the product descriptor "Clearer Thinking" were available for sale starting in January 2011. (Olson Decl. ¶¶ 21—23 and Ex. C.)

24. Beginning in or around late 2012, the labels for Prevagen products contained the product descriptor "Improves Memory." Prevagen products with labels bearing the product descriptor "Improves Memory" were available for sale starting in December 2012. (Olson Decl. ¶¶ 25—27 and Ex. D.)

25. In or around 2016, all of the Prevagen Products were reformulated to include Vitamin D3. The labels for each Prevagen Product that contained Vitamin D3 were changed to reflect the fact that the product now contained Vitamin D3. Prevagen Products with labels reflecting the addition of Vitamin D3 were available for sale starting in the fall of 2016. (Olson Decl. ¶¶ 28—30 and Ex. E.)

THE ADVERTISING CHALLENGED IN THE COMPLAINT

26. None of the advertisements featured in the Complaint are currently being used in the marketplace in the form challenged in the Complaint. (Olson Decl. ¶ 32.)

27. In or around May 2016, the graph featured on the Prevagen package depicted in Exhibit A of the Complaint was removed. (Olson Decl. ¶ 33.)

28. Defendants have no intention of disseminating the graph depicted in Exhibit A of the Complaint in the future in any marketing or advertising material relating to Prevagen without including one of the Qualifiers (defined at ¶ 45) (Olson Decl. ¶ 33.)

29. The advertisement included as Exhibit B of the Complaint stopped being disseminated in the form challenged in the Complaint. (Olson Decl. ¶ 34.)

30. Quincy has no intention of disseminating the advertisement depicted in Exhibit B of the Complaint in the future without including one of the Qualifiers. (Olson Decl. ¶ 34.)

31. The versions of the Prevagen website pages attached as Exhibit C of the Complaint were removed on or about March 2016. Exhibit C of the Complaint is not the current version of the website and has not been since on or about March 2016. (Olson Decl. ¶ 35.)

32. Quincy has no intention of disseminating the website page depicted in Exhibit C of the Complaint in the future. (Olson Decl. ¶ 35.)

33. The Fourth Edition of the Brain Health Guide, attached as Exhibit D of the Complaint, was replaced with the Fifth Edition in or about the summer of 2016. (Olson Decl. ¶ 36.)

34. The Fourth Edition of the Brain Health Guide is no longer being disseminated by Defendants and Defendants have no intention of disseminating it in the future. (Olson Decl. ¶ 36.)

35. The infomercial included as Exhibit E of the Complaint began airing in or around June 2013 and stopped airing in or around June 2014. (Olson Decl. ¶ 37.)

36. Defendants have no intention of disseminating the infomercial included as Exhibit E of the Complaint (or any other infomercial) in the future. (Olson Decl. ¶ 37.)

37. The image of the bus depicted in Exhibit F of the Complaint is from the Better Memory Tour. The Better Memory tour occurred beginning in or about 2011. (Olson Decl. ¶ 38.)

38. The Better Memory Tour has not been active since 2015. Defendants have no intention of resuming it in the future. (Olson Decl. ¶ 38.)

THE COLLINS CLASS ACTION SETTLEMENT

39. On June 22, 2020 in the matter captioned *Collins, et al. v. Quincy Bioscience, LLC*, No. 1:19-cv-22864-MGC (S.D. Fla.), Quincy Bioscience, LLC, Quincy Bioscience Holding Company, Inc., Prevagen, Inc., Quincy Bioscience Manufacturing, LLC, Mark Underwood and Michael Beaman entered into a nationwide class action settlement resolving a series of class actions challenging the same marketing claims challenged in this Action. (the "*Collins* Settlement"). (Graham Decl. Ex. HH, *Collins* ECF No. 143-1.)

40. The *Collins* Settlement contained the following release:

> "Upon the Effective Date, and except as to such rights or claims as may be created by this Agreement, and in consideration for the Settlement benefits described in this Agreement, Plaintiffs and the Settlement Class fully release and discharge the Settling Defendants, and all of their present and former parent companies, subsidiaries, special purposes entities formed for the purpose of administering this Settlement, shareholders, owners, officers, directors, employees, agents, servants, registered representatives, attorneys, insurers, affiliates, and successors, personal representatives, heirs and assigns, retailers, suppliers, distributors, endorsers, consultants, and any and all other entities or persons upstream and downstream in the production/distribution channels (together, the "Discharged Parties") from all claims, demands, actions, and causes of action of any kind or nature whatsoever, whether at law or equity, known or unknown, direct, indirect, or consequential, liquidated or unliquidated, foreseen or unforeseen, developed or undeveloped, arising under common law, regulatory law, statutory law, or otherwise, whether based on federal, state or local law, statute, ordinance, regulation, code, contract, common law, or any other source, or any claim that Co-Lead Class Counsel, Plaintiffs' Counsel, Class Representatives, Additional Plaintiffs or Settlement Class Members ever had, now have, may have, or hereafter can, shall or may ever have against the Discharged Parties in any court, tribunal, arbitration panel, commission, agency, or before any governmental and/or administrative body, or any other

> adjudicatory body, on the basis of, arising from, or relating to the claims alleged in the Action and the Prevagen Actions."

(Graham Decl. Ex. HH, *Collins* ECF 143-1 at 12.)

41. The United States District Court for the Southern District of Florida subsequently found the terms of the *Collins* Settlement to be "fair, reasonable, and adequate," and incorporated them into a Preliminary Approval Order and Final Judgment and Order. (Graham Decl. Exs. II, JJ, *Collins* ECF Nos. 158, 200.)

42. On November 18, 2020, the United States District Court for the Southern District of Florida entered a Final Order and Judgment with respect to the *Collins* Settlement. (Olson Decl. ¶ 39; Graham Decl. Ex. JJ, *Collins* ECF No. 200.)

43. Under the *Collins* Settlement, any person who purchased Prevagen in the United States since it became available for sale in 2007 was entitled to obtain monetary relief and they were provided with injunctive relief. (Graham Decl. Ex. HH, *Collins* ECF No. 143-1.)

44. In exchange, class members released Quincy Bioscience, LLC, Quincy Bioscience Holding Company, Inc., Prevagen, Inc., Quincy Bioscience Manufacturing, LLC, Mark Underwood and Michael Beaman "from all claims, demands, actions, and causes of action of any kind or nature whatsoever" that they "ever had, now have, may have, or hereafter can, shall or may ever have against the [Defendants] in any court, tribunal, arbitration panel, commission, agency, or before any governmental and/or administrative body, or any other adjudicatory body, on the basis of, arising from, or relating to the claims alleged in the Action." (Graham Decl. Ex. HH, *Collins* ECF No. 143-1.)

45. As part of the *Collins* Settlement, Quincy Bioscience, LLC, Quincy Bioscience Holding Company, Inc., Prevagen, Inc., Quincy Bioscience Manufacturing, LLC, Mark

Underwood and Michael Beaman agreed to include in marketing relating to Prevagen one of two statements (referred to herein as the "Qualifiers") with the Challenged Claims:

i. Based on a clinical study of subgroups of individuals who were cognitively normal or mildly impaired. This product is not intended to diagnose, treat, cure, or prevent any disease.

ii. Based on results from two subgroups of individuals who participated in a randomized double blind placebo controlled clinical study. Participants in the two subgroups were cognitively normal or mildly impaired. This product is not intended to diagnose, treat, cure, or prevent any disease.

(Olson Decl. ¶ 40; Graham Ex. HH, *Collins* ECF No. 143-1 at 8.

46. Plaintiffs were notified of the *Collins* Settlement and were afforded an opportunity to object, but chose not to voice an objection when they appeared at the final approval hearing. (Graham Decl. Ex. KK, *Collins* ECF No. 162-2.)

47. Plaintiffs filed a letter on the *Collins* docket stating that their lack of objection to the settlement "should not be construed . . . as approval or disapproval." (Graham Decl. Ex. LL, *Collins* ECF No. 188.).

48. In fact, despite a comprehensive notice plan, only one objection to the *Collins* Settlement was filed by a serial objector. The *Collins* Court dismissed that objection. (Graham Decl. Exs. KK, NN *Collins* ECF Nos. 195 and 162-2.)

49. Following approval of the *Collins* Settlement, the Qualifiers were incorporated into all new advertising, labelling and marketing materials for Prevagen that made the marketing claims identified in the *Collins* Settlement. (Olson Decl. ¶ 41.)

50. None of the marketing claims identified in the *Collins* Settlement are currently being used in the marketplace in the form challenged in the Complaint, as they all contain one of the Qualifiers. (Olson Decl. ¶¶ 33, 44, 45.)

51. Plaintiffs concede that they are not seeking restitution on behalf of consumers whose claims were released by the *Collins* Settlement. (Graham Decl. Ex. NN, Plaintiffs' Responses and Reply Counter-Findings to Defendants' Proposed Findings of Fact, ¶ 113.)

PREVAGEN'S CURRENT LABELING AND ADVERTISING

52. In December 2020, the labels for all Prevagen Products were changed to include one of the Qualifiers: "Based on a clinical study of subgroups of individuals who were cognitively normal or mildly impaired." (Olson Decl. ¶ 42.)

53. Prevagen Products with this Qualifier were available for sale beginning in or around February 2021. (Olson Decl. ¶ 42.)

54. As a result of the *Collins* Settlement, Defendants have no intention of disseminating Prevagen Products without including one of the Qualifiers whenever the label uses one of the marketing claims set forth in the *Collins* Settlement agreement. (Olson Decl. ¶ 44; Graham Decl. HH, *Collins* ECF No. 143-1.)

55. As a result of the *Collins* Settlement, Defendants have no intention of claiming that Prevagen improves memory, improves memory within 90 days or any other period of time, or reduces memory problems associated with aging in any advertising or marketing materials for Prevagen in the future without including one of the Qualifiers. (Olson Decl. ¶ 45; Graham Decl. HH, *Collins* ECF No. 143-1.)

The Dietary Supplement Health & Education Act of 1994 & the FTC Guidance

56. In recognition of the health benefits of dietary supplements, Congress enacted the Dietary Supplement Health & Education Act of 1994 ("DSHEA"), Public Law 103-417, 103rd Congress. (Graham Decl. Ex. I, https://ods.od.nih.gov/About/DSHEA_Wording.aspx.)

57. DSHEA amended the Federal Food, Drug, and Cosmetic Act ("FDCA") to establish standards with respect to dietary supplements, and to create a new category of marketing claims for dietary supplements called "structure/function" claims. (Graham Decl. Ex. I, https://ods.od.nih.gov/About/DSHEA_Wording.aspx.)

58. In January 2002, the United States Food and Drug Administration ("FDA") issued the "Small Entity Compliance Guide on Structure/Function Claims." (Graham Decl. Ex. J, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/small-entity-compliance-guide-structurefunction-claims.)

59. Following the passage of DSHEA, the FTC issued "Dietary Supplements: An Advertising Guide For Industry" (the "FTC Guidance"). (Graham Decl. Ex. F, FTC Guidance at 1.)

60. The FTC Guidance has not been modified or changed since at least 2001. (Graham Decl. Ex. F, FTC Guidance at 31.)

61. The FTC website displaying the Guidance states that it is designed to "explain[] the how-tos of making sure your claims have appropriate scientific support." (Graham Decl. ¶¶ 8—10; Ex. H, https://www.ftc.gov/business-guidance/advertising-marketing/health-claims.)

62. The FTC Guidance was issued to answer the "many questions" DSHEA generated "about the FTC's approach to dietary supplement advertising." (Graham Decl. Ex. F, FTC Guidance at 1.)

63. The FTC Guidance is intended to help marketers understand how FTC law applies to the advertising of dietary supplements. (Graham Decl. Ex. F, FTC Guidance; Graham Decl. Ex. DD, Plaintiffs' Responses and Objections to Defendants' First Set of Interrogatories dated August 6, 2021 at Response No. 29.)

64. The FTC Guidance states that dietary supplement advertising "must be truthful, not misleading, and substantiated." (Graham Decl. Ex. F, FTC Guidance at 1.)

65. The FTC Guidance states that the substantiation standard for dietary supplements is "flexible," requiring only that advertisers of dietary supplements have "competent and reliable scientific evidence" to substantiate their claims. (Graham Decl. Ex. F, FTC Guidance at 3, 9.)

66. The FTC Guidance defines "competent and reliable scientific evidence" to mean "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area[.]" (Graham Decl. Ex. F, FTC Guidance at 9.)

67. Under the FTC Guidance, there is no fixed formula for the number or type of studies required for dietary supplement advertising substantiation; nor is there a fixed formula for more specific protocol parameters like sample size and study duration. (Graham Decl. Ex. F, FTC Guidance at 8, 9.)

68. Randomized human clinical trials are not required under the FTC Guidance to substantiate dietary supplement marketing claims. (Graham Decl. Ex. F, FTC Guidance at 9-18.)

69. The FTC Guidance states that the FTC will consider all forms of competent and reliable scientific research when evaluating substantiation, including, but not limited to, animal studies, *in vitro* studies, epidemiological evidence, and all forms of human studies. (Graham Decl. Ex. F, FTC Guidance at 10.)

70. The FTC Guidance states that "[t]he FTC's standard for evaluating substantiation is sufficiently flexible to ensure that consumers have access to information about emerging areas of science." (Graham Decl. Ex. F, FTC Guidance at 8.)

71. The FTC Guidance states that "[s]tudies cannot be evaluated in isolation," and that the FTC looks to the "totality of the evidence" in evaluating substantiation. (Graham Decl. Ex. F, FTC Guidance at 12, 14.)

72. There is no requirement in the FTC Guidance that a claim regarding a dietary supplement be supported by any specific number of studies. (Graham Decl. Ex. F, FTC Guidance at 10.)

73. The FTC Guidance states that there is no set protocol for how to conduct research that will be acceptable under the substantiation doctrine and that studies cannot be evaluated in isolation. (Graham Decl. Ex. F, FTC Guidance at 12, 14.)

74. Quincy reviewed, consulted and relied upon the FTC Guidance when considering and creating marketing and advertising claims for Prevagen. (Underwood Decl. ¶ 10.)

75. Quincy has engaged outside counsel to review the available scientific evidence relating to apoaequorin and vitamin D and cognitive function to confirm that the labels and advertisements for Prevagen comply with all applicable laws and regulations, including the Guidance. (Underwood Decl. ¶ 11; Underwood 30(b)(6) Tr. 148:13—21; Underwood Indiv. Tr. 60:6-9, 85:2—86:17.)

76. Quincy's outside counsel has also been involved with the creation, editing, review, clearance, approval, placement and/or dissemination of labels and advertisements for Prevagen. (Underwood Decl. ¶ 12.)

77. Neither Plaintiff has issued any specific regulation or guidance prohibiting statistical analysis of a subgroup of participants of a clinical study to substantiate efficacy claims for dietary supplement products. (Graham Decl. Ex. EE, Plaintiffs' Supplemental Responses and Objections to Defendants' Requests for Admission dated August 6, 2021, at Response No. 36.)

78. Neither Plaintiff has issued any specific regulation or guidance mandating that statistical significance must be found in the entire population of a clinical study to substantiate efficacy claims for dietary supplement products. (Graham Decl. Ex. EE, Plaintiffs' Supplemental Responses and Objections to Defendants' Requests for Admission dated August 6, 2021, at Response No. 39.)

79. Neither Plaintiff has issued any specific regulation or guidance specifying the threshold of statistical significance required to substantiate efficacy claims for dietary supplement products. (Graham Decl. Ex. EE, Plaintiffs' Supplemental Responses and Objections to Defendants' Requests for Admission dated August 6, 2021, at Response No. 59.)

80. Despite issuing the FTC Guidance to industry, Plaintiffs have taken the position in this case that "[t]he term 'dietary supplement' has no legal meaning or significance under the FTC Act and New York laws at issue in this case." (Graham Decl. Ex. EE, Plaintiffs' Supplemental Responses and Objections to Defendants' Requests for Admission dated August 6, 2021, at Response Nos. 1, 8.)

81. Plaintiffs have taken the position that "[a]s applied to the claims challenged in this case, competent and reliable scientific evidence means randomized, controlled human clinical studies ('RCTs') that are well-designed, well-conducted, and properly analyzed according to standards generally accepted by experts in the relevant field." (Graham Decl. Ex. EE, Plaintiffs' Supplemental Responses and Objections to Defendants' Requests for Admission dated August 6, 2021, at Response Nos. 1, 8.)

82. Plaintiffs' experts have stated that a RCT is required to substantiate the Challenged Claims. (Graham Decl. Ex. T, Sano Aff. Report ¶ 28.)

SCIENTIFIC SUBSTANTIATION FOR PREVAGEN

Animal Studies

83. In or about November 2004, Quincy entered into a research agreement with the Neurophysiology and Behavior Laboratory, University of Wisconsin-Milwaukee (the "Lab"). The Lab has conducted, and continues to conduct, numerous studies on apoaequorin in animal models. (Graham Decl. Ex. FF, Defendants' Fourth Supplemental Responses and Objections to Plaintiffs' First Set of Interrogatories, at Response No. 2; Underwood Decl. ¶¶ 13—15 and Exs. A—L.)

84. Results of animal and *in vitro* studies performed at the Lab consistently reported that apoaequorin provides a cognitive benefit, including neuroprotective effects. (Graham Decl. Ex. FF, Defendants' Fourth Supplemental Responses and Objections to Plaintiffs' First Set of Interrogatories, at Response No. 2; Underwood Decl. ¶ 14 and Ex. A—M.)

85. Certain results of animal studies performed at the Lab that reported apoaequorin's neuroprotective effects were published in a peer-reviewed journal: Detert JA, et al., *Pretreatment with apoaequorin protects hippocampal CA1 neurons from oxygen-glucose deprivation*, PLos One, 2013; 8(11):e790002. (Graham Decl. Ex. FF, Defendants' Fourth Supplemental Responses and Objections to Plaintiffs' First Set of Interrogatories, at Response No. 2; Underwood Decl. ¶ 16 and Ex. M.)

Canine Studies

86. In addition to the studies performed by the Lab, Quincy has also sponsored research on apoaequorin through canine models, which reported that apoaequorin provides beneficial cognitive effects. (Underwood Decl. ¶¶ 17—18 and Exs. N, O; Graham Decl. Exs. D, S, CC, Gortler Tr. 174:14-21; Kurzer Tr. 102:2-10; Underwood 30(b)(6) Tr. 42:20—43:6.)

87. Results from Quincy's canine studies reporting apoaequorin's beneficial cognitive effects in canines were published in a peer-reviewed journal: N. Milgram et al., *A novel mechanism for cognitive enhancement in aged dogs with the use of a calcium-buffering protein*, Journal of Veterinary Behavior 10 (2015) 217-222 (Underwood ¶ 19 and Ex. O.)

88. Results from Quincy's canine studies are particularly persuasive given that dogs provide a natural animal model for mild cognitive dysfunction in humans. (Graham Decl. Ex. R, Kurzer Aff. Report ¶ 30.)

Open Label Human Clinical Research on Prevagen

89. Between approximately May 2008 and January 2009, Quincy conducted an open label clinical trial (the "Open Label Trial") consisting of approximately 55 adult participants to assess the impact of apoaequorin on general health and quality of life, including cognitive function. (Graham Decl. Ex. FF, Defendants' Fourth Supplemental Responses and Objections to Plaintiffs' First Set of Interrogatories, at Response No. 2; Underwood Decl. ¶ 20 and Ex. P at 149862.)

90. Participants in the Open Label Trial received 10 mg of apoaequorin per day over 90 days and responded to a battery of questions from the SF-36 Survey, a standardized measure of health status, and ERA-38 Survey, the purpose of which is to measure changes in expectations regarding aging among older adults. (Graham Decl. Ex. FF, Defendants' Fourth Supplemental Responses and Objections to Plaintiffs' First Set of Interrogatories, at Response No. 2; Underwood Decl. Ex. P at 149865.)

91. The Open Label Trial reported a statistically significant benefit on questions related to cognitive function, fatigue, sleep, and general health for participants. (Graham Decl. Ex. FF,

Defendants' Fourth Supplemental Responses and Objections to Plaintiffs' First Set of Interrogatories, at Response No. 2; Underwood Decl. Ex. P at 149865.)

92. In or about 2014, Sunsho Pharmaceuticals, Ltd. conducted a human clinical trial testing the efficacy of Prevagen on cognitive functioning and quality of sleep. Fifteen men and woman aged forty and above were administered 1 capsule of Prevagen every morning for 30 days. (Graham Decl. Ex. FF, Defendants' Fourth Supplemental Responses and Objections to Plaintiffs' First Set of Interrogatories, at Response No. 2; Underwood Decl. ¶ 32 and Ex. U, QUI-FTCNY-00096934-00096953 p. 2.)

93. The Sunsho trial reported that, after 30 days of intake of Prevagen, there was "a confirmed rise in the score which showed a statistically significant difference from the score before intake" and that "the effect of 'Prevagen' can be considered to be favorable from the viewpoint of its use as a brain supplement." (Underwood Decl. Ex. U; Graham Decl. Ex. Q, Katz Tr. 113:17—114:7.)

94. Neither Plaintiffs, nor anyone acting on their behalf, including their experts, have conducted or caused to be conducted any human clinical research involving Prevagen. (Graham Decl. Ex. EE, Plaintiffs' Supplemental Responses and Objections to Defendants' Requests for Admission dated August 6, 2021, at Response No. 17.)

95. Neither Plaintiffs, nor anyone acting on their behalf, including their experts, have conducted or caused to be conducted any human clinical research involving apoaequorin. (Graham Decl. Ex. EE, Plaintiffs' Supplemental Responses and Objections to Defendants' Requests for Admission dated August 6, 2021, at Response No. 18.)

Madison Memory Study

96. Between 2009 and 2011, Quincy conducted the Madison Memory Study, a 90-day randomized, double-blind, placebo-controlled study designed "to determine whether Prevagen with apoaequorin (10 mg) improves quantitative measures of cognitive function in community dwelling, older adults." (Compl. ¶ 28; Underwood Decl. ¶ 21 and Ex. Q at 1, 8.) Kenneth C. Lerner, *Madison Memory Study: A Randomized, Double-Blinded, Placebo-Controlled Trial of Apoaequorin in Community-Dwelling, Older Adults*, at 1 (Aug. 1, 2016) ("MMS")

97. For the Madison Memory Study, 218 adults aged 40 to 95, each with self-reported memory difficulties, were randomly assigned to receive either apoaequorin capsules or placebos, and were instructed to take one capsule per day. (Underwood Decl. ¶ 22 and Ex. Q at 1, 4.)

98. Examiners obtained a baseline cognitive score for each participant using an eight-question screening tool called AD8, used to differentiate between adults facing normal cognitive aging and those with early signs of dementia. (Underwood Decl. ¶ 23 and Ex. Q at 1.)

99. AD8 scores of 0 to 2 are generally considered reflective of normal aging or "very mild" cognitive impairment—i.e. healthy, older adults. (Underwood Decl. ¶ 24 and Ex. Q at 2, 4.)

100. Participants with AD8 scores of 0 to 2 were the target population for the Madison Memory Study. (Underwood Ex. Decl. ¶ 24 and Ex. Q, MMS at 2, 4; Graham Decl. Ex. A, Lerner Indiv. Tr. 124:17-126:2; Graham Decl. Ex. O, Katz Aff. Report ¶ 32; Graham Decl. Ex. W, Schwartz Aff. Report ¶ 67; Graham Decl. Ex. Z, Wei Reb. Report ¶¶ 32-33.)

101. The recruitment materials from the Madison Memory Study were targeted towards healthy, older adults (i.e. those with AD8 scores between 0 and 2). (Underwood Decl. ¶ 29 and Ex. S.)

102. While Quincy did not exclude any participants based on AD8 score, the Madison Memory Study used an AD8 score of 2 as a cut-off value to discriminate between those people who are cognitively normal or who have mild or very mild cognitive impairment (AD8 0-2) versus those with higher levels of impairment (AD8 3-8). (Underwood Ex. Decl. ¶ 24 and Ex. Q at 2, 4; Graham Decl. Ex. B, Lerner 30(b)(6). Tr. 66:17—67:13 ; Graham Decl. Ex. O, Katz Aff. Report ¶ 32; Graham Decl. Ex. W, Schwartz Aff. Report ¶ 67; Graham Decl. Ex. Z, Wei Reb. Report ¶¶ 32—33.)

103. The protocol for the Madison Memory listed a planned sample size of 100 participants. (Underwood Ex. Decl. ¶ 25 and Ex. R.)

104. The Madison Memory Study included 100 participants who reported an AD8 score of 0-2. The remaining participants in the Madison Memory Study reported AD8 scores higher than 2. (Underwood Ex. Decl. ¶ 26 and Ex. Q at 5.)

105. On days zero, eight, 30, 60, and 90, participants completed nine quantitative computerized tests designed to measure several areas of cognitive function. (Underwood Decl. Ex. Q at 1-2.)

106. The nine quantitative computerized tests were selected from the Cogstate Research Battery—a "widely used neuropsychological battery of computerized cognitive tests"—which measured a variety of aspects of cognitive function, including verbal learning, memory, executive function, visual learning, psychomotor function, and working memory. (Compl. Ex. C(12); Underwood Decl. Ex. Q at 1.)

107. Quincy decided to analyze the Madison Memory Study participant data based on AD8 scores before the Madison Memory Study commenced. (Graham Decl. Ex. A, Lerner Indiv. Tr. 124:17—126:2; Underwood Decl. ¶ 28.)

108. At the end of 90 days, Quincy analyzed and reported on the data from all 218 participants, as well as a number of subgroups of participants, including the AD8 0-1 and AD8 0-2 study groups that matched the target study population. (Underwood Decl. Ex. Q at 5—6.)

109. The Madison Memory Study demonstrated statistically significant results in the AD8 0-1 and AD8 0-2 targeted study groups, which "contain individuals with either minimal or no cognitive impairment, and are the appropriate population for a dietary supplement intended to support people with mild memory loss associated with aging." (Underwood Decl. Ex. Q at 4.)

110. The Madison Memory Study results showed that participants in the treatment group with AD8 scores of 0-2 showed statistically significant improvements as compared to placebo recipients on three different Cogstate tests (Groton Maze Learning, One Card Learning, and Identification) and outperformed the placebo group on four additional tests. (Underwood Decl. Ex. Q at 6—9.)

111. Madison Memory Study participants in the treatment group with AD8 scores of 0-1 also experienced statistically significant improvements as compared to placebo recipients on three Cogstate tests (Groton Maze Recall, Detection, and One Card Learning) and outperformed the placebo group on four additional tests. (Underwood Decl. Ex. Q at 9.)

112. The placebo group did not show any statistically significant improvement as compared to the treatment group on any of the Cogstate states in the AD8 0-1 and AD 0-2 subgroups. (Underwood Ex. Q at 6—9.)

113. Because Prevagen is "intended for healthy, non-demented individuals," results from the AD8 0-1 and AD8 0-2 subgroups were considered "the most relevant to the efficacy of the product." (Underwood Decl. Ex. Q at 1; Graham Decl. Ex. B, Lerner 30(b)(6) Tr. 66:5-13.)

114. The Madison Memory Study concluded that "Prevagen demonstrated the ability to improve aspects of cognitive function in older participants with either normal cognitive aging or very mild impairment, as determined by AD8 screening." (Underwood Decl. Ex. Q at 8; Compl. ¶ 29 (acknowledging "positive findings").)

115. In 2016, *Advances in Mind Body Medicine* published a peer-reviewed paper titled, "Effects of a Supplement Containing Apoaequorin on Verbal Learning in Older Adults in the Community," which reported on a subset of results from the Madison Memory Study (the "*Advances* Publication"). (Underwood Ex. Decl. ¶ 30 and Ex. T.)

Vitamin D

116. The Recommended Dietary Intake for Vitamin D is 600 IU/day for people from 1-70 years of age, and 800 IU/day for people over 70 years of age. (Graham Decl. Ex. R, Kurzer Aff. Report ¶ 17.)

117. The prevalence of vitamin D deficiency in adults in the United States is approximately 40%. (Graham Decl. Ex. R, Kurzer Aff. Report ¶ 59.)

118. There is a vast body of scientific literature supporting a relationship between vitamin D, which has been part of Prevagen's formulation since 2016, and improved cognitive function. This evidence includes RCTs, meta-analyses, cross-sectional studies, and prospective studies that demonstrate beneficial associations between higher vitamin D *intake* and cognitive function, as well as higher vitamin D *levels* and cognitive function. (Graham Decl. Ex. R, Kurzer Aff. Report ¶¶ 60-69.)

119. Animal studies also suggest that vitamin D influences neuronal development, neuroplasticity, neuronal growth, and neuroprotection. (Graham Decl. Ex. R, Kurzer Aff. Report ¶ 60.)

120. Given the prevalence of vitamin D deficiency in adults in the United States and the low levels of vitamin D being consumed by most people, this large body of scientific evidence supplements the research set forth herein on apoaequorin and confirms that the Challenged Claims are supported by competent and reliable scientific evidence. (Graham Decl. Ex. R, Kurzer Aff. Report ¶¶ 58-78.)

The Parties' Experts

121. Quincy's experts have specialties in the relevant fields of internal medicine, nutrition, neuroscience, dietary supplement substantiation, epidemiology, and biostatistics. (Graham Decl. Ex. M, Alexander Aff. Report ¶¶ 5, 8—16; Graham Decl. Ex. W, Schwartz Aff. Report ¶¶ 18—80; Graham Decl. Ex. R, Kurzer Aff. Report ¶¶ 30—84; Graham Decl. Ex. O, Katz Aff. Report ¶¶ 11—37, 50—70; Graham Decl. Ex. Z, Wei Reb. Report ¶¶ 10—55.)

122. Quincy's experts evaluated Quincy's body of scientific substantiation in accordance with the flexible, totality of the evidence approach set forth in the Guidance, and all concluded that the Challenged Claims are substantiated by competent and reliable scientific evidence. (Graham Decl. Ex. M, Alexander Aff. Report ¶¶ 5, 8—16; Graham Decl. Ex. W, Schwartz Aff. Report ¶¶ 18—80; Graham Decl. Ex. R, Kurzer Aff. Report ¶¶ 30—84; Graham Decl. Ex. O, Katz Aff. Report ¶¶ 11—37, 50—70; Graham Decl. Ex. Z, Wei Reb. Report ¶¶ 10—55; Graham Decl. Ex. F, FTC Guidance at 9—18.)

123. Quincy's experts have confirmed that Quincy has amassed significantly more scientific substantiation than what is typically seen in the dietary supplement industry. (Graham Decl. Ex. W, Schwartz Rebuttal Report ¶¶ 9, 22.)

124. Plaintiffs' experts did not review any aspect of the FTC Guidance in forming their opinions in this Action. (Graham Decl. Ex. N, Berg Tr. 34:8-16; Graham Decl. Ex. BB, Wittes

Tr. 33:6-9, 52:18—54:13; Graham Decl. Ex. U, Sano Tr. 36:16-21, 39:21—41:13; Graham Decl. Ex. V, Sano Decl. ¶¶ 2—7.)

125. Plaintiffs' expert, Jeremy M. Berg, PhD, testified that he was not familiar the Guidance. (Graham Decl. Ex. N, Berg Tr. 34:14-16.)

126. Plaintiffs' expert, Mary Sano, PhD, testified that she was not familiar with the Guidance. (Graham Decl. Ex. U, Sano Tr. 39:21-24.)

127. Plaintiffs' expert, Janet Wittes, PhD, testified that she had never viewed the Guidance. (Graham Decl. Ex. BB, Wittes Tr. 52:18—53:14.)

128. Dr. Berg was not familiar with the "competent and reliable scientific evidence" standard that applies to dietary supplement marketing claims when he was deposed. (Graham Decl. Ex. N, Berg Tr. 34:8-16; 90:6-9.)

129. Dr. Sano was not familiar with the "competent and reliable scientific evidence" standard that applies to dietary supplement marketing claims when she was deposed. (Graham Decl. Ex. U, Sano. Tr. 37:18—38:11, 39:12—41:8; Graham Decl. Ex. V, Sano Decl. ¶¶ 2—7.)

130. Dr. Wittes was not familiar with the "competent and reliable scientific evidence" standard that applies to dietary supplement marketing claims when she was deposed. (Graham Decl. Ex. BB, Wittes Tr. 35:19—37:18.)

131. Plaintiffs' experts did not review any marketing material for Prevagen, have no experience in marketing, offered no opinion relating to how consumers would interpret or perceive the Challenged Claims, and therefore offer no opinion as to whether the Challenged Claims are "likely to mislead consumers acting reasonably under the circumstance." (Graham Decl. Ex. U Sano Tr. 40:24—41:4, 50:14-24, 54:4-17, 63:3—64:7, 170:2-14, 266:2-7; Graham Decl. Ex. BB, Wittes Tr. 35:12-18, 38:23—39:2, 51:7—52:6; Graham Decl. Ex. N, Berg Tr. 44:3-6, 110:7-24.)

132. Plaintiffs proffered no expert testimony on consumer perception. (Graham Decl. Ex. U, Sano Tr. 40:24—41:4, 50:7-20, 54:4-17, 63:3—64:7, 170:2-14, 266:2-7; Graham Decl. Ex. BB, Wittes Tr. 35:12-18, 38:23—39:2, 51:7—52:6; Graham Decl. Ex. N, Berg Tr. 44:3-6, 110:7-24.)

133. Plaintiffs proffered no expert testimony regarding the net impression on consumers of any advertisement or marketing material relating to Prevagen. (Graham Decl. Ex. U, Sano Tr. 40:24—41:4, 50:7-20, 54:4-17, 63:3—64:7, 170:2-14, 266:2-7; Graham Decl. Ex. BB, Wittes Tr. 35:12-18, 38:23—39:2, 51:7—52:6; Graham Decl. Ex. N, Berg Tr. 44:3-6, 110:7-24.)

134. Plaintiffs proffered no consumer survey evidence that reflects consumers' interpretation of any advertisement or marketing material relating to Prevagen. (Graham Decl. Ex. EE, Plaintiffs' Supplemental Responses and Objections to Defendants' Requests for Admission dated August 6, 2021, at Request Nos. 24-25.)

135. Plaintiffs proffered no expert evidence relating to any aspect of the marketing of Prevagen. (Graham Decl. Ex. U, Sano Tr. 40:24—41:4, 50:14-24, 54:4-17, 63:3—64:7, 170:2-14, 266:2-7; Graham Decl. Ex. BB, Wittes Tr. 35:12-18, 38:23—39:2, 51:7—52:6; Graham Decl. Ex. N, Berg Tr. 44:3-6, 110:7-24.)

136. Plaintiffs proffered no expert evidence relating to consumers' perception of any aspect of the marketing of Prevagen. (Graham Decl. Ex. U, Sano Tr. 40:24—41:4, 50:14-24, 54:4-17, 63:3—64:7, 170:2-14, 266:2-7; Graham Decl. Ex. BB, Wittes Tr. 35:12-18, 38:23—39:2, 51:7—52:6; Graham Decl. Ex. N, Berg Tr. 44:3-6, 110:7-24.)

137. Plaintiffs did not provide Dr. Wittes with documents relating to Prevagen's substantiation other than the Madison Memory Study. (Graham Decl. Ex. AA, Wittes Report Ex. B.)

138. Dr. Sano reviewed Quincy's animal, *in vitro* and open label studies on apoaequorin, but considered them to be irrelevant. (Graham Decl. Ex. T, Sano Aff. Report ¶¶ 15, 29, 42.)

139. Drs. Sano and Wittes testified that they did not know when any of the analyses for the Madison Memory Study were conducted, in what order the analyses for the Madison Memory Study were conducted, or which Madison Memory Study analyses were planned and which were exploratory. (Graham Decl. Ex. U, Sano Tr. 182:11—189:12; 204:18—210:15; Graham Ex. BB, Wittes Tr. 111:8-16, 114:7—116:9.)

140. Dr. Wittes testified that "[a] post hoc analysis is usually defined as an analyses that is done that has not been prespecified and that is done after whoever is doing the analysis looks at the data." (Graham Decl. Ex. BB, Wittes Tr. 90:19-25.)

141. Dr. Sano testified that she had not seen any documents setting forth when any subgroup analysis was conducted, and that she assumed they were conducted after the "entire study population" was analyzed. (Graham Decl. Ex. U, Sano Tr. 182:11—189:12; 204:18—210:15.)

142. Dr. Wittes testified that she did not know when the AD8 0-1 or AD8 0-2 data analyses were planned, and that she did not know when or in what order any of Quincy's analyses were conducted. (Graham Decl. Ex. BB, Wittes Tr. 111:8-16, 114:7—116:9.)

143. Subgroup analyses, and even *post hoc* subgroup analyses, are not only common, but are published in peer-reviewed journals. (Graham Decl. Ex. W, Schwartz Aff. Report ¶¶ 66—68 and Appendix 1; Graham Decl. Ex. O, Katz Aff. Report ¶¶ 62—66.

ADUHELM

144. On June 7, 2021, the FDA granted accelerated approval for the drug, aducanumab (marketed as Aduhelm) for the treatment of Alzheimer's Disease. (Graham Decl. Ex. K, Pam Belluck, *F.D.A. Panel Declines to Endorse Controversial Alzheimer's Drug*, N.Y. Times (Nov.

16, 2020), https://www.nytimes.com/2020/11/06/health/aducanumab-alzheimers-drug-fda-panel.html; Pam Belluck and Rebecca Robbins, *F.D.A. Approves Alzheimer's Drug Despite Fierce Debate Over Whether It Works*, N.Y. Times (June 7, 2021), https://www.nytimes.com/2021/06/07/health/aduhelm-fda-alzheimers-drug.html.)

145. Aduhelm is intended for the treatment of Alzheimer's Disease, based on an unplanned analysis of a small subgroup of participants from two separate clinical trials including approximately 3,200 total participants. (Graham Decl. Ex. L, *Aducanumab*, LiverTox: Clinical and Research Information on Drug-Induced Liver Injury, National Institute of Diabetes and Digestive and Kidney Diseases (last updated June 9, 2021), https://www.ncbi.nlm.nih.gov/books/NBK571858/.)

146. Both of those clinical trials were terminated early due to the lack of evidence of efficacy and the severe side effects that were being observed in study participants. (Graham Decl. Ex. X, Schwartz Rebuttal Report ¶¶ 23—26; Graham Decl. Ex. Y, Schwartz Tr. 235:6-13; Graham Decl. Ex. P, Katz Rebuttal Report ¶¶ 31—36; Graham Decl. Ex. K.)

PRE-LITIGATION INVESTIGATION AND LITIGATION

147. On or about July 22, 2015, the FTC issued a Civil Investigative Demand to Quincy Bioscience Holding Company, Inc. ("CID"). (Underwood Decl. ¶ 33.)

148. Defendants produced over 200,000 pages of discovery to the FTC in connection with the CID. (Graham Decl. ¶ 47.)

149. Quincy and its counsel participated in meetings with the FTC in connection with the CID. (Underwood Decl. ¶ 34.)

150. Defendants produced nearly 200,000 pages of discovery to Plaintiffs in response to Plaintiffs' document requests in this Action. (Graham Decl. ¶ 48.)

151. Plaintiffs took thirteen depositions in this Action. (Graham Decl. ¶ 46.)

152. The Court previously ordered Plaintiffs to produce a "sampling" of the challenged advertisements that it intended to pursue at trial. (Graham Decl. ¶ 44) (ECF No. 148.)

153. In response, Plaintiffs provided a list of over 1,600 pages of marketing material produced in discovery, as well as various categories of additional documents that are not identified by bates number. (Graham Decl. ¶ 45 and Ex. OO, Plaintiffs' Responses to Quincy's Second Set of Interrogatories dated May 19, 2021 and Amended Ex. A.)

154. Plaintiffs did not seek a preliminary injunction or a temporary restraining order at any time in this Action. (Graham Decl. ¶ 50.)

155. The FTC has not filed a complaint against Defendants pursuant to its administrative process or otherwise pursued an adjudicative proceeding against Defendants, other than this action. (Underwood Decl. ¶ 35.)

Dated: April 14, 2022

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